



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/031,862	02/27/98	BUSSELL	L

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NM12/0128

EXAMINER

SPIVACK, P

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 01/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/013,862

Applicant(s)
Bussell, L.

Examiner
Phyllis G. Spivack

Group Art Unit
1614



☒ Responsive to communication(s) filed on Nov 17, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 4-8 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 4-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicant's Amendment and Information Disclosure Statement filed November 17, 1998, Paper No. 4, are acknowledged. Claims 1-3 are canceled. New claims 4-8 are presented and represent all of the claims now under consideration.

Applicant is requested to send a copy of the Information Disclosure Statement submitted on February 27, 1998 when responding to this Office Action. Failure to comply with this request will result in a delay in the prosecution of the subject application.

In the last Office Action the claims were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Newly presented claims 4-8 contain no parenthetical subject matter. Further, an active step "comprises administering" is included in the language of claim 4. Accordingly, these rejections of record are withdrawn.

However, the assertion that the Markush language "selected from the group consisting of" followed by "but is not limited to" is deemed improper. Accordingly, the rejection of claim 5 under 35 U.S.C. 112, second paragraph, is maintained.

Following entry of claim 4, wherein a method of treating bacterial infections of the skin caused by organisms susceptible to fluoroquinolone antibiotics is clearly the method of use contemplated, the rejection of record under 35 U.S.C. 112, first paragraph, is withdrawn.

In the last Office Action claims 1-3 were rejected under 35 U.S.C. 103 as being unpatentable over Sato et al., U.S. Patent No. 5,401,741, in view of Remington's Pharmaceutical Sciences.

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It was asserted Sato teaches topical formulations comprising the fluoroquinolone antibiotic ofloxacin for treating a bacterial infection. See column 1, lines 63-64, where application of an ointment is to the external auditory canal. Remington establishes the utility of both acetone and alcohol as commonly used solvents. The Applicant argues fluoroquinolones and alcohol and acetone have been utilized for years but have never been combined into one topical preparation. It is alleged that improved antibiotic activity is seen with the combination. In the absence of a comparative showing of such results, the rejection of record under 35 U.S.C. 103 is maintained. The selections of optimal concentrations of the antibiotic, acetone and alcohol are parameters well within the purview of those skilled in the art of formulation chemistry through no more than routine experimentation.

No claim is allowed.

Grohe, U.S. Patent No. 4,844,902, is cited to show further the state of the art with respect to topically applicable preparations of fluoroquinolone type antibiotics in the form of an ointment, gel, emulsion, cream, spray, powder, paste, solution and plaster where an alcohol is part of the formulation.

In response to Applicant's request for constructive assistance and suggestions from the Examiner, an attempt was made to reach the Applicant by phone. No phone number was available.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Phyllis spivack whose telephone number is 703-308-4703.

January 22, 1999

Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**